K002142

JAN 2 9 2002

510(k) Summary

1.0 GENERAL INFORMATION

1.1 This submission is made by

EMT-Rx
9400 Ransdell Road
Suite 10
Raleigh, NC 27603-8980
Robert J. Bard, Esq,
919.552.9689

1.2 Purpose of Submission

1.2.1 This submission is intended to notify the Federal Food and Drug Administration that EMT-Rx is preparing to market saline IV flush syringes in various sizes and fill volumes.

1.3 The Saline IV Flush Syringes are identical to the existing legally marketed empty disposable plastic (polypropylene) syringes currently in distribution except that the devices presented here are pre-filled with 0.9% NaCl (normal saline) and Sodium Chloride Injection USP that is used to fill the syringes.

1.4 Trade Name: Normal Saline IV Flush Syringe

1.5 Common Name: 0.9% Sodium Chloride Injection USP

1.6 Classification Name: Device, flush, vascular access

1.7 Product Code: NGT

1.8 Device Classification: Class II

1.9 Classification Panel: General Hospital and Personal Use Device

1.10 Statement of Equivalence

1.10.1 The EMT-Rx Saline IV Flush Syringe is substantially equivalent to the ROCAP Norm 31 Saline IV Flush Syringe (K984614), the Baxter 0.9% Sodium Chloride Flush Syringe (K984590) and the Excelsior Disposable syringe w/normal saline (0.9%) (K962938).

2.0 PERFORMANCE STANDARDS

2.1 There are no known performance standards for flush syringes.

3.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Description of Device

3.1.1 The Saline Flush Syringe is a single use device.

3.1.2 The products use standard off the shelf plastic syringes prefilled with Sodium Chloride Injection USP (0.9% NaCl). The syringes used in these devices are devices that have been granted permission to market.

4.0 INTENDED USE

4.1 The sterile Saline IV Flush Syringe is intended to maintain patency of indwelling venous access devices. The device is to be used for flushing of IV catheters and IV tubing both before and after administration of intermittent medication.

5.0 BIOLOGICAL SPECIFICATIONS

5.1 Biological testing is in conformance with either USP Class VI plastic test and/or ISO 10993 Part 1 for all fluid path components,

6.0 LABELS AND LABELING

6.1 EMT-Rx believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.0 CHEMISTRY

7.1 The device is filled with Sodium Chloride Injection USP (0.9% NaCl).

8.0 PACKAGING

8.1 Each syringe is packaged using a Doboy Stratus Wrapper.

8.2 The Saline Flush Syringes are packed 30 in a shelf pack and four to eight shelf packs to a shipping carton.

9.0 COMPARISON TO LEGALLY MARKETED DEVICES

9.1 9.1Comparison to the ROCAP (K984614), Baxter (K984590) and Excelsior (K962938) prefilled syringes

9.1.1 The devices tinder review and the predicate devices are pre-filled with USP 0.9% NaCl

9.1.2 The devices under review and the predicate devices are indicated for intravenous delivery of medication and to be used for flushing of IV catheters and IV tubing both before and after administration of intermittent medication.

9.1.3 The devices under review and the predicate devices are single use disposable products.

9.2 Specifications

9.2.1 The device under review and the predicate use syringes in the same sizes and fill volumes (3 ml, 6 ml and 12 ml syringes).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2002

Mr. Robert J. Bard
EMT-RX
9400 Ransdell Road, Suite 10
Raleigh, North Carolina 27603

Re: K002142
Trade/Device Name: Normal Saline IV Flush Syringe
Regulation Number: 880.5200
Regulation Name: 0.9% Sodium Chloride Injection, USP
Regulatory Class: II
Product Code: NTG
Dated: October 20, 2001
Received: November 5, 2001

Dear Mr. Bard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002142

510(k) Number (if known): _____

Device Name: Saline IV Flush Syringe

Indications for Use:

The sterile Saline Flush Syringe is intended to maintain patency of indwelling venous access devices. The device is to be used for flushing of IV catheters and IV tubing both before and after administration of intermittent medication.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Alicia Cicconi
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002142